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6. Respondent's understanding of her relationship with EHG was merely that of an independent contractor, retained only for the purpose of reading radiological studies performed at EHG; Respondent was paid on a per reading basis for studies that were delivered to her in her office by employees of EHG. Interpretations were made at that separate location, and picked up with the transcription of the report and returned to EHG by EHG employees. In connection with EHG, Mr. Carrai had indicated that EHG was operating legally and in compliance with the law. Dr. Enriquez therefore specifically denies the allegations of **paragraph 7.** of the Complaint.
7. Respondent is without knowledge of the allegations made in **paragraphs 8 through 12** of the Complaint.
8. Respondent is completely without any knowledge regarding the allegations of **paragraphs 13 through 23** of the Complaint; When respondent was approached by Carrai to read films performed at EHG, she was only aware that they had already been operating, presumably legally, and Carrai had indeed represented the same to her. She was not approached by Carrai to serve as "lead interpreting physician" as far as she understood and was therefore not on the premises of EHG since films were delivered to her for interpretation.
9. Respondent has no recollection of specifically signing an application to the ACR on behalf of EHG; She does recall being requested to sign some papers which Mr. Carrai represented were necessary as a radiologist who interpreted films from EHG; She never discussed, nor was she informed that she was intended to serve as anything other than an independent contractor for EHG to read x-ray studies; further, she was never informed of the issues with certification by ACR, but rather was fraudulently informed by Carrai that the films were being legally performed. The Allegations of **paragraph 24.** are therefore denied.
10. Respondent is without knowledge of the alleged dealings between ACR and EHG alleged in **paragraphs 25 through 28** of the Complaint, and therefore denies the same and demands strict proof thereof.
11. Respondent denies the allegations of **paragraph 29** of the complaint as they specifically relate to her; she is without knowledge of the same as they relate to the other respondents.

Dr. Enriquez is not an owner, employee, principal or facility under the Mammography Quality Standards Act (MQSA) and was unaware of the certification problems alleged in the Complaint. She was the victim of the fraudulent acts of the individuals at EHG who knowingly and purposefully hid certification information from her.

12. No correspondence was received by Respondent as alleged in **paragraph 30.** of the complaint and if any correspondence were sent to her at the EHG address, they were concealed from her and Respondent therefore denies the allegations thereto.
13. The Respondent was only requested to interpret films by the principals at EHG, which was done in her office; Respondent was therefor not on the premises of EHG where the provisional certificate would have been and therefore denies the allegations of **paragraph 31.**
14. Respondent denies any liability for penalties under the MQSA, was not, in her relationship with EHG a person or entity that can be penalized under such Act, and did not knowingly, intentionally or puposefully read any films from an uncertified facility and did not aid or abet the other respondents in illegal conduct. Respondent therefore denies any penalty or liability alleged in **paragraphs 31 through 37** of the F.D.A.'s Complaint and paragraphs 1 through 15 of the F.D.A.'s Prayer for Relief.

DEFENSES

1. Respondent, Erlinda Enriquez, M.D., was neither an owner or principal of Ecumed Health Services, Inc. In her capacity, she was not aware of the laws pertaining to certification nor had she agreed to become responsible for the same; any readings she performed, documents she signed, or other actions taken were at the request of respondents Carrai and Reyes who represented that they were appropriately certified and that she was assuming no further responsibilities.
2. If any actions taken by Respondent Enriquez somehow permitted the other respondents to operate without certification, it was unintentional and without any knowledge that she could be doing the same; Dr. Enriquez was never informed of the apparent abundance of issues between EHG and the ACR, the fact that the ACR certification related to F.D.A certification

under the MQSA or the that EHG were not in compliance with the laws in this respect.

3. Had Dr. Enriquez been made aware of any illegal, unregistered, unlicensed activities, she would not have hesitated to take appropriate action, including reporting Ecumed to the authorities as she did when he learned of other potentially illegal conduct by Mr Carrai in May of 2003.
4. Respondent Enriquez was herself a victim of the apparent fraudulent conduct by the other respondents who purposefully and knowingly misrepresented EHG's status, withheld crucial information from her and possibly obstructed her receipt of U.S. Mail addressed to her at the EHG address.

EXCEPTIONS TO THE REQUESTED PENALTY

Dr. Enriquez vehemently denies any liability to a penalty as alleged in the Complaint; however pursuant to 21 C.F.R. 17.9(b)(3), in the event the Administrative Law Judge were to find that a penalty should be assessed the following mitigating factors should be considered.

1. Dr. Enriquez was the victim of misrepresentations by Carrai and Reyes regarding the status of EHG's certification and the legality of their operations, Dr. Enriquez was not requested to provide any other services and did not have, in fact, further access to the facility. She was never told that Dr. Stone was no longer associated with the clinic.
2. Dr. Enriquez discovered, on or about April of 2003, that Carrai had apparently interpreted films on his own and forged Dr. Enriquez' signature. Immediately upon learning the same, she informed Mr. Carrai of her intention to disassociate with EHG completely. Mr. Reyes then introduced himself as an owner and provided respondent with a document in which Mr. Carrai admitted responsibility for such actions and resigned from EHG. She continued to read studies for EHG because of documentation provided to her indicating that Mr. Carrai was no longer involved with EHG.
3. Upon learning of the apparent illegal conduct by Mr Carrai, and despite receiving his admission and evidence that he had disassociated with EHG, Dr Enriquez reported Mr.

Carrai to the Florida Department of Health for the unlicensed practice of Medicine; Such conduct clearly indicates **no** intention on Dr. Enriquez' behalf to aid or abet any type of illegal behavior. Dr Enriquez also demanded assurances from Reyes no other studies existed that were not interpreted by a physician.

4. Dr. Enriquez was not paid or contracted to perform any services for Ecumed beyond receiving \$12.00 per mammogram interpretation; she received no other compensation or stipend which would indicate that she had been retained as a medical director, lead interpreting radiologist or in another position with supervisory responsibilities.
5. To assess a penalty of \$1,000.00 per film, when Dr. Enriquez receive only \$12.00 to read mammogram makes the requested penalty excessive, unconscionable and far beyond an appropriate penalty.
6. As stated above, Mr. Carrai admitted to having interpreted some studies fraudulently as if they had been read by Dr. Enriquez; There is therefore no way to confirm that there were indeed 653 studies actually interpreted by Dr. Enriquez as alleged in the Complaint and is used as the basis for the penalty calculation.

RESPONDENT ENRIQUEZ'S COUNSEL

Dr. Erlinda Enriquez is represented by counsel as follows:

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CERTIFICATE OF SERVICE

I hereby certify that original Answer and Defenses of Respondent Erlinda B. Enriquez, M.D. was sent by Federal Express Airbill # 533 / 1755 4451 to the Division of Dockets Managements, Food and Drug Administration, 5630 Fishers Lane, Room 1061 (HA-

305), Rockville, MD 20852 on this 19 day of August, 2004, and to Michael N. Varrone, Department of Health and Human Services, Office of the General Counsel, Food and Drug Division, 5600 Fishers Lane, Room 6-39 (GCF-1), Rockville MD 20857.

Respectfully submitted this 19 day of August, 2004,

A handwritten signature in black ink, appearing to read "S. R. Ballinger", is written over a horizontal line.

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